



# STATE OF CONNECTICUT

OFFICE OF PROTECTION AND ADVOCACY FOR  
PERSONS WITH DISABILITIES  
60B WESTON STREET, HARTFORD, CONNECTICUT 06120-1551

September 14, 1999

U.S. Department Of Health and Human Services  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20857

Re: Proposed Methadone Treatment Regulations – Docket No. 98N-0617

Dear Sir or Madam,

I am writing on behalf of this agency to comment upon the proposed regulations to amend 21 CFR Part 291 and 42 CFR Part 8 concerning Methadone Treatment, that were published in the July 22, 1999 edition of the *Federal Register*. This agency has authority to educate federal policy makers on matters that may impact the rights of individuals with disabilities. e.g. 42 U.S.C. §10801 *et seq.*

There are three (3) areas of concern that this agency would recommend changes in the proposed regulations. The agency's comments are as follows:

- 42 CFR §8.12(b) should be revised to expressly require a treatment program to comply with the provisions of the *Americans with Disabilities Act*, 42 U.S.C. §10201 *et seq.* and Section 504 of the *Rehabilitation Act of 1973*, as amended. 29 U.S.C. §794. Treatment programs are recipients of federal financial assistance, 45 CFR Part 84, and they are a place of public accommodations. 28 CFR Part 36. However, this agency has been advised by such programs that neither the ADA or Section 504 provisions are applicable. Amending the treatment standards to expressly include compliance with specific civil rights laws, rather than "pertinent" federal laws, should be required as part of the certification process.

98N-0617

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Page two

September 14, 1999

- 42 CFR §8.4(e) should be amended to require a treatment program to provide a patient with access to an independent complaint/grievance procedure. The proposed standard does not contain such a requirement as currently drafted. The independent complaint/grievance process should require a posting of the complaint procedure in a conspicuous place, an investigation of the complaint by an independent person not directly associated with the issues or individuals involved with the complaint, a timely resolution of the complaint such as the five (5) day timeline in the proposed regulations, continuation of the service during the pendency of the complaint in the absence of exigent circumstances, an opportunity to appeal the decision to a neutral person or entity, and safeguards that a treatment program will not retaliate against the patient for exercising his or his rights under this section.
- 42 CFR §8.12(i) should be amended by adding a section (ix) to the *Unsupervised and take home use* criteria, so as to require the medical director to consider the effects of a patient's mental and/or physical disability, if any, to determine eligibility for this benefit. There are situations whereby a patient's mental or physical disability could prevent him or her from having routine access to a treatment program. Thus, the disability or the manifestation of the disability may limit the persons' routine access to the program due to this issue. The medical director should be authorized to consider the effects of a patient's disability or the manifestation of the disability, in addition to other regulatory factors, as part of the process for authorizing a request for *Unsupervised or take home use*.

This agency appreciates the opportunity to comment upon the proposed federal regulations.

Thank you in advance for your time and consideration.

Sincerely,

  
Lawrence W. Berliner  
General Counsel

STATE OF CONNECTICUT  
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